

JUDGE WOODS

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BICKEL & BREWER,

Plaintiff,

v.

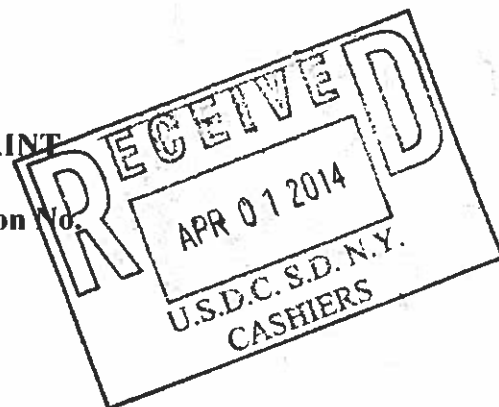
**UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, and
NATIONAL INSTITUTE OF
ENVIRONMENTAL HEALTH
SCIENCES,**

Defendants.

14 CV 2278

COMPLAINT

Civil Action No.



Plaintiff Bickel & Brewer (“Bickel & Brewer” or “Plaintiff”) files this Complaint against the United States Department of Health and Human Services (“DHHS”) and the National Institute of Environmental Health Sciences (“NIEHS”) (collectively, “Defendants”), based on personal knowledge as to itself and upon information and belief as to all other matters, as follows:

I.

NATURE OF THE ACTION

1. Plaintiff has commenced this action to compel Defendant NIEHS to comply with its obligation to provide Plaintiff with the records and information Plaintiff has requested under the Freedom of Information Act (the “Act” or “FOIA”).

2. Plaintiff made its initial request for information under FOIA to the NIEHS Administrator on May 7, 2013. In the course of its correspondence with Plaintiff over the next four months, the NIEHS withheld or redacted alleged confidential commercial

information under FOIA exemption 4. The NIEHS violated FOIA by improperly withholding or redacting information that is neither confidential nor commercial.

3. Plaintiff timely filed an administrative appeal to the DHHS on October 2, 2013. To date, DHHS has entirely failed to respond to this appeal. The DHHS has violated FOIA by failing to reply to Plaintiff's administrative appeal within twenty business days.

4. This action seeks an order declaring that the NIEHS is in violation of FOIA by improperly withholding or redacting information, an order declaring that the DHHS is in violation of FOIA by failing to respond to Plaintiff's administrative appeal, an order compelling the NIEHS to provide to Plaintiff complete and unredacted copies of all non-exempt requested information, and an award of costs and reasonable attorneys' fees incurred by Plaintiff in this action.

II.

JURISDICTION AND VENUE

5. The Court has subject matter jurisdiction pursuant to:

- a. 5 U.S.C. § 552(a)(4)(B), because Plaintiff resides in the Southern District of New York; and
- b. 28 U.S.C. § 1331, because the United States District Courts possess general federal question jurisdiction for claims arising under the laws of the United States.

6. Pursuant to 28 U.S.C. § 1391(e)(1)(C), venue is proper in the Southern District of New York because Defendants are agencies of the United States, Plaintiff resides in this District, and no real property is involved in this action.

III.

PARTIES

7. Plaintiff Bickel & Brewer is a Texas general partnership with its principal place of business in Dallas, Texas and an office in New York, New York.

8. Defendant DHHS is a department of the United States federal government, with headquarters located in Washington, D.C. The DHHS is federal agency within the meaning of 5 U.S.C. § 552(f)(1).

9. Defendant NIEHS is a subdivision of the DHHS, with headquarters located in Research Triangle Park, North Carolina. The NIEHS is a federal agency within the meaning of 5 U.S.C. § 552(f)(1).

IV.

FACTUAL BACKGROUND

A. Plaintiff's Initial FOIA Request Dated May 7, 2013.

10. From 2004 until at least 2012, Dr. Philippe Grandjean ("Grandjean"), Professor of Environmental Medicine at the University of Southern Denmark and Adjunct Professor of Environmental Health at the Harvard School of Public Health, conducted Study ES012199 entitled *Epidemiology of Immunotoxicant Exposure in Children* (the "Study") to examine the effect of environmental chemicals, including perfluorochemicals ("PFCs"), on the immune system of children in a North Atlantic fishing community. The Study was funded, in whole or in part, by the NIEHS.

11. Grandjean published two articles related to the Study: (1) Grandjean, P., *Serum Vaccine Antibody Concentrations in Children Exposed to Perfluorinated Compounds*, 307 JAMA 4, 391-97 (2012); and (2) Grandjean, P., *Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations*

in children, 12 Environmental Health 35 (2013) (collectively, the “Grandjean Publications”).

12. 3M Company (“3M”) produced PFCs for use in a variety of consumer, commercial, and industrial products sold throughout the world. In December 2010, the State of Minnesota (the “State”) brought suit against 3M (the “Minnesota Action”), alleging that PFCs cause adverse health and environmental effects, and 3M’s discharge of PFCs caused damage to the State’s natural resources.

13. Plaintiff represents 3M in the Minnesota Action. The Study and subsequent Grandjean Publications are relevant to the Minnesota Action.

14. On May 7, 2013, pursuant to FOIA, Plaintiff made a written request (the “FOIA Request”) to the NIEHS. A true and correct copy of the FOIA Request is attached hereto as Exhibit A. The FOIA Request sought:

- a. all non-exempt records maintained by the NIEHS relating to all data supplied by or to the authors or researchers of the Study;
- b. all non-exempt records maintained by the NIEHS relating to all communications to or from the authors, researchers, or anyone on either’s behalf;
- c. all non-exempt records maintained by the NIEHS relating to all records of funding, grants, stipends, and payments by the NIEHS to the authors or researchers of the Study;
- d. all non-exempt records maintained by the NIEHS relating to any proposals, grant applications, or other methods utilized to select this Study for support;
- e. all non-exempt records maintained by the NIEHS relating to all drafts, interim reports, Study updates, or other indicia of Study progress; and
- f. all non-exempt records maintained by the NIEHS relating to all drafts, review copies, or input requests regarding the final Study report.

B. NIEHS's Acknowledgment Letter Dated May 21, 2013.

15. On May 21, 2013, the NIEHS sent a letter to Plaintiff acknowledging receipt of Plaintiff's FOIA Request (the "NIEHS Acknowledgement Letter"). A true and correct copy of the NIEHS Acknowledgement Letter is attached hereto as Exhibit B.

16. In the NIEHS Acknowledgement Letter, the NIEHS indicated its intent to expunge "social security numbers, birth dates, percentages of effort, institutional base salary, source of private support, pending support, and any patentable material wherever they appear throughout the grant material," as per DHHS policy. The NIEHS also stated that "the priority score, direct costs recommended, evaluation, opinion, and information pertaining to the budget recommendation are also expunged from the summary statements." The NIEHS stated that if Plaintiff felt that such information should not be excluded from the material, Plaintiff was invited to advise the NIEHS accordingly so that the National Institutes of Health's ("NIH") Freedom of Information Officer could be consulted.

C. Plaintiff's Objection Letter Dated May 30, 2013.

17. Plaintiff objected to the NIEHS's intention of excluding certain information from the material. In a letter dated May 30, 2013 ("Plaintiff's May 30 Objection Letter"), Plaintiff objected to the exclusion of "all information regarding the [S]tudy's funding, including: (1) the source of private funding[;] and (2) pending support for the [S]tudy." A true and correct copy of Plaintiff's May 30 Objection Letter is attached hereto as Exhibit C.

D. NIEHS's Partial Response Letter Dated July 22, 2013.

18. On July 22, 2013, the NIEHS sent a partial response letter to Plaintiff (the "Partial Response"), attaching 191 pages responsive to categories 2, 3, and 5 of Plaintiff's

FOIA Request. A true and correct copy of the Partial Response is attached hereto as Exhibit D.

19. In the Partial Response, the NIEHS stated that it was continuing its search and review of responsive records and would continue to make records available as the review was completed.

20. The NIEHS also stated that it had expunged the following information per DHHS policy: “percentage of effort, references to unpublished articles, birth dates, percentile, priority score, evaluative comment, account number and PIN number wherever they appear through the grant material.” The NIEHS had not previously stated in any prior correspondence that all references to published articles and evaluative comment would be expunged.

21. Further, the NIEHS indicated that, “in the spirit of FOIA,” it had consulted Grandjean concerning patent rights and other confidential commercial or financial information which would merit exclusion under 5 U.S.C. § 552(b)(4). The NIEHS stated that the Partial Response reflected Grandjean’s advice and, as such, a significant number of documents were withheld or redacted as “confidential commercial information.” The NIEHS again invited Plaintiff to advise in writing if Plaintiff felt that materials had been omitted that should have been made available.

E. Plaintiff’s Second Objection Letter Dated August 19, 2013.

22. In a letter to the NIEHS dated August 19, 2013 (“Plaintiff’s August 19 Objection Letter”), Plaintiff raised several issues regarding the Partial Response. A true and correct copy of Plaintiff’s August 19 Objection Letter is attached hereto as Exhibit E. Specifically, Plaintiff raised the following three issues:

- a. Plaintiff objected in its May 30 Objection Letter to the exclusion of information regarding the Study's funding, including: (1) the source of private funding; and (2) pending support for the Study. In Plaintiff's August 19 Objection Letter, Plaintiff stated that the Partial Response did not address how any responsive information subject to Plaintiff's objection was treated and accordingly sought clarification from the NIEHS.
- b. Plaintiff objected to any redactions of references to unpublished articles and evaluative comment, because the NIEHS Acknowledgement Letter did not indicate possible redactions of such information in the Partial Response.
- c. The NIEHS failed to provide annual progress reports for each year of the Study. The NIEHS responded to Category 5 of Plaintiff's request, which sought, *inter alia*, "indicia of Study progress," by providing responsive annual progress reports for only the years 2004-05. Moreover, the annual progress reports for the years 2004-05 indicated researchers provided raw data gathered during the Study. The raw data would be responsive to category 1 of the FOIA Request. Accordingly, Plaintiffs requested that data as well.

F. NIEHS's Final Response Letter Dated September 6, 2013.

23. On September 6, 2013, the NIEHS sent a final response to Plaintiff (the "Final Response"), which contained 325 additional pages responsive to categories 2, 4, and 5 of Plaintiff's FOIA Request. A true and correct copy of the Final Response is attached hereto as Exhibit F.

24. In the Final Response, the NIEHS clarified that references to unpublished articles and evaluative comments were also expunged per DHHS policy, and that notification of such was inadvertently omitted from the NIEHS Acknowledgement Letter.

25. The NIEHS also produced annual progress reports for the years 2006-07 and 2011-12. However, the NIEHS failed to produce annual progress reports for the years 2008-10. Additionally, in response to Plaintiff's request for raw data provided by Grandjean, the NIEHS confirmed that no raw data was provided to the NIEHS.

26. Further, the NIEHS reiterated that, “in the spirit of FOIA,” it had consulted Grandjean concerning patent rights and other confidential commercial or financial information which would merit exclusion under 5 U.S.C. § 552(b)(4) and that the Final Response reflected that advice. As in the Partial Response, there was no indication as to what extent Grandjean’s advice was considered, yet a significant number of documents were again withheld or redacted as “confidential commercial information.”

27. Finally, the NIEHS advised Plaintiff of its right to appeal the Final Response, and directed Plaintiff to appeal, if it so desired, in writing within thirty days to the Director, News Division, Office of the Assistant Secretary for Public Affairs, DHHS. The NIEHS also provided addresses to which an administrative appeal should be sent.

G. Plaintiff’s Administrative Appeal To The DHHS Dated October 2, 2013.

28. Plaintiff timely appealed the NIEHS Final Response on October 2, 2013, by written letter to the Director, News Division, Office of the Assistant Secretary for Public Affairs, DHHS (the “Appeal”). The Appeal was delivered and received on October 4, 2013. A true and correct copy of the Appeal, including an affidavit of delivery, is attached hereto as Exhibit G.

29. Plaintiff appealed to the DHHS based on the following:

- a. In the materials responsive to category 5 of the FOIA Request, the NIEHS produced annual progress reports for the years 2007-07 and 2011-12. Annual progress reports for the years 2008-10 should have been produced.
- b. It was unclear in the Partial and Final Responses as to what degree Grandjean’s advice regarding the scope of withheld or redacted information was considered as it pertained to patent rights and other confidential commercial or financial information. Accordingly, there was no indication of whether the NIEHS performed an independent assessment of whether the information in question should be disclosed as required under FOIA.

- c. Of the 325 pages produced in the Final Response, significant portions were redacted as “confidential commercial information” under 5 U.S.C. § 552(b)(4). Plaintiff contends that the redacted information is neither confidential nor commercial and, as such, must be produced to Plaintiff.

30. Plaintiff has not received any response from the DHHS. On January 3, 2014, sixty business days after the DHHS received Plaintiff’s Appeal, Plaintiff wrote a letter to the Director, News Division, Office of the Assistant Secretary for Public Affairs, DHHS (“Plaintiff’s January 3 Letter”) inquiring as to the status of the Appeal. Plaintiff informed the DHHS that if it did not respond to the Appeal by January 31, 2014, Plaintiff would be forced to bring an action under the Administrative Procedure Act to obtain necessary relief. A true and correct copy of Plaintiff’s January 3 Letter, attaching a true and correct copy of the Appeal, is attached hereto as Exhibit H.

31. As of April 1, 2014, more than one-hundred and twenty business days after the DHHS received Plaintiff’s Appeal, Plaintiff still has not received a response of any kind.

32. The inaction of the DHHS constitutes a violation of 5 U.S.C. § 552(a)(6)(A)(ii). The DHHS was obligated to make a determination with respect to the Appeal within twenty business days of receipt of the Appeal, but has failed to do so.

33. Pursuant to 5 U.S.C. § 552(a)(6)(C)(i), Plaintiff has exhausted its applicable administrative remedies.

34. Plaintiff, therefore, brings this action to compel the NIEHS to produce complete and unredacted copies of all non-exempt documents requested in Plaintiff’s Appeal.

V.

CLAIMS FOR RELIEF

CLAIM 1

(Improper Withholding of NIEHS Records)

35. Plaintiff repeats and incorporates the allegations set forth above in Paragraphs 1 through 34 hereof as if fully set forth herein.

36. Based on the above facts and legal obligations, the NIEHS is subject to a duty to provide the records requested by Plaintiff.

37. In its Partial and Final Responses, the NIEHS improperly asserted the privilege of 5 U.S.C. § 552(b)(4), which exempts from disclosure information that is related to trade secrets and privileged or confidential commercial or financial information obtained by a person from whom documents were requested. The withheld or redacted documents are neither confidential nor commercial.

CLAIM 2

(Failure to Reply to FOIA Administrative Appeal)

38. Plaintiff repeats and incorporates the allegations set forth above in Paragraphs 1 through 37 hereof as if fully set forth herein.

39. Based on the above facts and legal obligations, the DHHS was required to respond to Plaintiff's Appeal of the NIEHS Final Response.

40. The DHHS received Plaintiff's Appeal on October 4, 2013. Under 5 U.S.C. § 552(a)(6)(A)(ii), the DHHS is required to make a determination with respect to any appeal within twenty business days after the receipt of such appeal. The deadline by which the DHHS was required to respond was November 2, 2013.

41. By failing to timely respond to Plaintiff's Appeal, the DHHS violated 5 U.S.C. § 552(a)(6)(A)(ii).

42. By improperly asserting the privilege of 5 U.S.C. § 552(b)(4), the NIEHS violated 5 U.S.C. § 552(a)(3), which requires the NIEHS to make any non-exempt documents promptly available to Plaintiff upon any request for such documents.

CLAIM 3

(Recovery of Costs and Fees)

43. Plaintiff repeats and incorporates the allegations set forth above in Paragraphs 1 through 42 hereof as if fully set forth herein.

44. The failure of the DHHS to timely respond to Plaintiff's Appeal has forced Plaintiff to bring this action and incur costs and fees of no less than \$10,000.

45. Accordingly, pursuant to 5 U.S.C. § 552(a)(4)(E), Plaintiff is entitled to recover its costs and reasonable attorneys' fees.

VI.

PRAYER

WHEREFORE Plaintiff respectfully requests that this Court:

1. Declare that the NIEHS was not justified in asserted the privilege of 5 U.S.C. § 552(b)(4) and thus improperly withheld or redacted NIEHS documents;

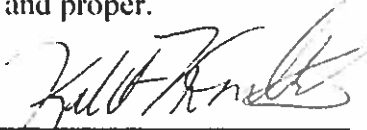
2. Declare that the DHHS failed to timely respond to Plaintiff's Appeal in violation of 5 U.S.C. § 552(a)(6)(A)(ii);

3. Direct the NIEHS to immediately produce complete and unredacted copies of all documents requested in Plaintiff's Appeal;

2. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and

3. Grant Plaintiff all other relief that is just and proper.

Dated: April 1, 2014



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Stephanie L. Gase
BICKEL & BREWER
1717 Main Street
Suite 4800
Dallas, Texas 75201
Tel. (214) 653-4000
Fax: (214) 653-1015

-and-

Kaleb McNeely
Joshua T. Ebersole
767 Fifth Avenue
New York, New York 10153
Tel. (212) 489-1400
Fax: (212) 489-2384

Exhibit A

BICKEL & BREWER

ATTORNEYS AND COUNSELORS

1717 MAIN STREET

SUITE 4800

DALLAS, TEXAS 75201

PHONE: (214) 853-4000

FAX: (214) 853-1015

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May 6, 2013

VIA CERTIFIED MAIL# 7001 2510 0001 9697 7760

Kim Minneman
Freedom of Information Act Coordinator
National Institute of Environmental Health Sciences
111 T. W. Alexander Drive
Research Triangle Park, NC 27709

Re: Freedom of Information Act Request

Dear Ms. Minneman:

Pursuant to 5 U.S.C. section 552 *et seq.*, of the Freedom of Information Act ("FOIA"), please provide copies of *all* non-exempt records maintained by the National Institute of Environmental Health Sciences ("NIEHS") regarding the following:

Study 5 R01 ES012199 08, Grandjean, P. *Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations in children*, 12 ENVIRONMENTAL HEALTH 35 (2013) (the "Study"), supported in whole or in part by the NIEHS. A copy of the publication is attached for your convenience.

This request includes but should not be limited to the following information regarding the Study: (1) all data supplied by or to the authors or researchers of the Study; (2) all communications to or from the authors, researchers or anyone on either's behalf; (3) all records of funding, grants, stipends and payments by the National Institute of Environmental Health Sciences to the authors or researchers of the Study; (4) any proposals, grant applications or other methods utilized to select this Study for support; (5) all drafts, interim reports, study updates or other indicia of study progress; and (6) all drafts, review copies or input requests regarding the final study report.

This request is not for commercial use.

May 6, 2013

Page 2

We are willing to pay fees for this request up to a maximum of \$1000.00. If you estimate that the fees will exceed this limit, please inform me first.

Sincerely,


Darla Gabbitas

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2124-07



RESEARCH

Open Access

Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations in children

Philippe Grandjean^{1,2*} and Esben Budtz-Jørgensen³

Abstract

Background: Immune suppression may be a critical effect associated with exposure to perfluorinated compounds (PFCs), as indicated by recent data on vaccine antibody responses in children. Therefore, this information may be crucial when deciding on exposure limits.

Methods: Results obtained from follow-up of a Faroese birth cohort were used. Serum-PFC concentrations were measured at age 5 years, and serum antibody concentrations against tetanus and diphtheria toxoids were obtained at age 7 years. Benchmark dose results were calculated in terms of serum concentrations for 431 children with complete data using linear and logarithmic curves, and sensitivity analyses were included to explore the impact of the low-dose curve shape.

Results: Under different linear assumptions regarding dose-dependence of the effects, benchmark dose levels were about 1.3 ng/mL serum for perfluorooctane sulfonic acid and 0.3 ng/mL serum for perfluorooctanoic acid at a benchmark response of 5%. These results are below average serum concentrations reported in recent population studies. Even lower results were obtained using logarithmic dose-response curves. Assumption of no effect below the lowest observed dose resulted in higher benchmark dose results, as did a benchmark response of 10%.

Conclusions: The benchmark dose results obtained are in accordance with recent data on toxicity in experimental models. When the results are converted to approximate exposure limits for drinking water, current limits appear to be several hundred fold too high. Current drinking water limits therefore need to be reconsidered.

Keywords: Benchmark dose, Developmental exposure, Immunotoxicity, Perfluorinated compounds, Risk assessment

Background

Perfluorinated compounds (PFCs) have been in use for over 60 years in a wide array of applications. PFCs were first manufactured in the US from about 1947, with perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) as primary products [1]. PFC was later found to contaminate ground and surface water, and PFOS was found to accumulate in freshwater fish [2]. These compounds possess a strong carbon-fluorine bond, which leads to persistence of the PFCs in the environment and the human body [2]. Thus, the high thermal, chemical

and biological inertness that make the PFCs useful for many industrial purposes at the same time also generates an environmental hazard.

Serum-PFC analyses conducted by the Centers for Disease Control and Prevention (CDC) show that PFOS and PFOA are detectable in virtually all Americans [3], with children often showing higher serum concentrations than adults [4]. Analyses of paired samples of maternal serum and cord serum show that PFCs are transferred through the human placenta [5,6]. Due to global dissemination of PFCs, their serum concentrations in children and pregnant women even in the remote locations, such as the Faroe Islands [7], are similar to US levels. Exposures to some PFCs in the Faroes may occur primarily through marine diets [8]. Despite the extensive use of these compounds for many decades, and the persistence and

* Correspondence: pgrandjean@uhh.dk

¹Department of Environmental Medicine, University of Southern Denmark, Odense, Denmark

²Department of Environmental Health, Harvard School of Public Health, Boston, MA 02215, USA

Full list of author information is available at the end of the article



Exhibit B



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Phone: 919-541-3411
Fax: 301-451-5756
E-mail: minneman@niehs.nih.gov

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233, MD K3-16
Research Triangle Park, NC 27709-2233

May 21, 2013

Darla J. Gabbitas
Bickel & Brewer
1717 Main Street, Suite 4800
Dallas, TX 75201

Re: FOI Case No. 41328

Dear Ms. Gabbitas:

This acknowledges your May 7, 2013, Freedom of Information Act (FOIA) request (amended from May 6, 2013) addressed to me. You requested a copy of all non-exempt records maintained by the National Institute of Environmental Health Sciences ("NIEHS") regarding Study ES012199, supported in whole or in part by the NIEHS, which has resulted in published articles and which may have generated unpublished data and findings (the "Study"), as follows:

- (1) Grandjean, P., *Serum Vaccine Antibody Concentrations in Children Exposed to Perfluorinated Compounds*, 307 JAMA 4, 391-97 (2012). You provided a copy of the publication.
- (2) Grandjean, P., *Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations in children*, 12 Environmental Health 35 (2013). You provided a copy of the publication.

This request includes but should not be limited to the following information regarding the Study:

1. All data supplied by or to the authors or researchers of the Study;
2. All communications to or from the authors, researchers or anyone on either's behalf;
3. All records of funding, grants, stipends and payments by the NIEHS to the authors or researchers of the Study;
4. Any proposals, grant applications or other methods utilized to select this Study for support;
5. All drafts, interim reports, study updates or other indicia of study progress; and
6. All drafts, review copies or input requests regarding the final study report

We will send you all material consistent with the exemptions recognized by the FOIA. It is Department of Health and Human Services (DHHS) policy to expunge social security numbers,

Page 2 - Darla J. Gabbitas

birth dates, percentage of effort, institutional base salary, source of private support, pending support, and any patentable material wherever they appear throughout the grant material. The priority score, direct costs recommended, evaluation, opinion, and information pertaining to the budget recommendation are also expunged from the summary statements. If you feel that this information should not be excluded from the material, please advise me and I will consult with the NIH Freedom of Information Officer.

We are asking the grantee to advise this office if release of the material you requested will adversely affect any patent rights or reveal other confidential commercial or financial information. Subsequent to receipt of such advice this office will make a decision regarding releasability. We will do everything possible to comply with your request in a timely manner.

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the DHHS FOIA regulations as they apply to commercial-use requesters; i.e., you will be charged for duplication at 10-cents per page; and for search and review time at the hourly rate (\$23.00, \$46.00, \$83.00) of the searcher and reviewer. Please be advised that the DHHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA's nine exemptions. If there are any fees associated with processing this request, you will be sent an invoice with our final response. Your \$1,000.00 fee limit is noted and we will contact you if we expect the fees to exceed that amount.

Please feel free to contact me at the phone number or e-mail address shown above for additional information or to inquire about the status of your request.

Sincerely,



Kim L. Minneman
Freedom of Information Coordinator

Exhibit C

BICKEL & BREWER

ATTORNEYS AND COUNSELORS

1717 MAIN STREET

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DALLAS, TEXAS 75201

PHONE: (214) 653-4000

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May 30, 2013

VIA ELECTRONIC MAIL: minneman@niehs.nih.gov

Kim Minneman
Freedom of Information Act Coordinator
National Institute of Environmental Health Sciences
111 T. W. Alexander Drive
Research Triangle Park, NC 27709

Re: Freedom of Information Case No. 41328

Dear Ms. Minneman:

Thank you for your letter dated May 21, 2013, regarding the above referenced FOIA request. Your letter indicates your intention to "expunge" certain information throughout the grant materials. While we do not object to redacting most of the information you have listed, we do object and our request specifically encompasses obtaining all information regarding the study's funding, including: (1) the source of private funding and (2) pending support for the study.

As your letter requested, I am writing to advise of our narrow objection to the proposed redactions and will await the results of your conferral with the NIH Freedom of Information Officer.

Finally, we would request that you provide a time frame for ultimate receipt of the information contemplated by our FOIA request.

Thank you in advance of your kind attention.

Sincerely,

A handwritten signature in black ink, appearing to read 'Darla Gabbitas', with a stylized flourish at the end.

Darla Gabbitas

Exhibit D



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Phone: 919-541-3411
Fax: 301-451-5756
E-mail: minneman@niehs.nih.gov

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233, MD K3-16
Research Triangle Park, NC 27709-2233

July 22, 2013

Darla J. Gabbitas
Bickel & Brewer
1717 Main Street, Suite 4800
Dallas, TX 75201

Re: FOI Case No. 41328

Dear Ms. Gabbitas:

This is a partial response to your May 7, 2013, Freedom of Information Act (FOIA) request (amended from May 6, 2013) addressed to me. Your request was received in our office on May 14, 2013. You requested a copy of all non-exempt records maintained by the National Institute of Environmental Health Sciences ("NIEHS") regarding Study ES012199, supported in whole or in part by the NIEHS, which has resulted in published articles and which may have generated unpublished data and findings (the "Study"), as follows:

- (1) Grandjean, P., *Serum Vaccine Antibody Concentrations in Children Exposed to Perfluorinated Compounds*, 307 JAMA 4, 391-97 (2012). You provided a copy of the publication.
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This request includes but should not be limited to the following information regarding the Study:

1. All data supplied by or to the authors or researchers of the Study;
2. All communications to or from the authors, researchers or anyone on either's behalf;
3. All records of funding, grants, stipends and payments by the NIEHS to the authors or researchers of the Study;
4. Any proposals, grant applications or other methods utilized to select this Study for support;
5. All drafts, interim reports, study updates or other indicia of study progress; and
6. All drafts, review copies or input requests regarding the final study report

Enclosed are 191 pages responsive to your request. This consists of:

Responsive to Item 2: Correspondence for 5R01ES012199-04, 12 pages
Correspondence for 5R01ES012199-05, 11 pages

Page 2 - Darla J. Gabbitas

Responsive to Item 3: Notice of Grant Award for 1R01ES012199-01A1, 1 page
Notice of Grant Award for 5R01ES012199-02, 9 pages
Notices of Grant Award for 5R01ES012199-03, 18 pages
Grants Management Worksheets for 5R01ES012199-03, 6 pages
Notices of Grant Award for 5R01ES012199-04, 22 pages
Grants Management Worksheets for 5R01ES012199-04, 6 pages
Notices of Grant Award for 5R01ES012199-05, 15 pages
Grants Management Worksheets for 5R01ES012199-05, 15 pages
Notice of Grant Award for 5R01ES012199-06, 5 pages
Grants Management Worksheets for 5R01ES012199-06, 24 pages
Notices of Grant Award for 5R01ES012199-07, 10 pages
Grants Management Worksheets for 5R01ES012199-07, 10 pages
Notice of Grant Award for 5R01ES012199-08, 5 pages
Grants Management Worksheets for 5R01ES012199-08, 9 pages

Responsive to Item 5: Grant Progress Report for 5R01ES012199-02, 7 pages
Grant Progress Report for 5R01ES012199-03, 6 pages

It is Department of Health and Human Services (DHHS) policy to expunge percentage of effort, references to unpublished articles, birth dates, percentile, priority score, evaluative comment, account number and PIN number wherever they appear throughout the grant material. This information has been removed from the enclosed material.

Requesters who ask for grant applications usually want to receive only material that will help in understanding the process that led to the awards or to improve their own methods of drafting grant applications. Requesters usually do not want material that applicants believe would harm them if released. We have found that the spirit of the FOIA can be enhanced through a spirit of cooperation among requesters of materials and those who submitted the materials.

In this instance, we asked the grantee for advice concerning patent rights and other confidential commercial or financial information and the material that we are furnishing reflects that advice. If you feel that materials have been omitted that should have been made available to you, please write to me and I will consult with the NIH Freedom of Information Officer.

We are continuing our search and review of responsive records and will continue to make records available as the review is completed. If at any time you have questions about the status of your request, please feel free to contact me at the phone number or e-mail address shown above.

Sincerely,



Kim L. Minneman
Freedom of Information Coordinator

Enclosure:
191 pages

Exhibit E

BICKEL & BREWER

ATTORNEYS AND COUNSELORS

1717 MAIN STREET

SUITE 4800

DALLAS, TEXAS 75201

PHONE: (214) 653-4000

FAX: (214) 653-1015

Darla J. Gabbitas*
*Licensed in Colorado
www.bickelbrewer.com

787 FIFTH AVENUE
50TH FLOOR
NEW YORK, NEW YORK 10153
(212) 489-1400

August 19, 2013

VIA ELECTRONIC MAIL: minneman@niehs.nih.gov

Kim Minneman
Freedom of Information Act Coordinator
National Institute of Environmental Health Sciences
111 T. W. Alexander Drive
Research Triangle Park, NC 27709

Re: Freedom of Information Case No. 41328

Dear Ms. Minneman:

Thank you for the partial response sent on July 22, 2013 ("Partial Response") to the above referenced FOIA request. The material you provided addressed Categories 2, 3 and 5 of my request and I await additional production regarding the remaining requests. Please let me know when you anticipate providing a full response.

Regarding the materials that you have provided, I have three questions and would appreciate your responses, as discussed below.

First, we previously corresponded about the NIEHS's plan to "expunge" certain information throughout the grant materials. While I did not object to redacting most of the information listed in your May 21, 2013 letter, I did object to redacting information regarding the study's funding, including: (1) the source of private funding and (2) pending support for the study.¹ The Partial Response does not address how any responsive information subject to our objection was treated. Can you please let me know if you redacted any information regarding these two subcategories from your Partial Response. Please indicate with sufficient specificity what documents have been redacted and the location of any redactions made in the produced documents so that we may continue our dialogue to obtain the requested information.

Second, the Partial Response states that all references to unpublished articles and evaluative comment have been removed from the materials provided. However, your May 21, 2013 letter indicating possible redactions did not include these items. I object to the redaction of any responsive materials including references to unpublished articles and evaluation comment.

¹ See Gabbitas letter dated May 30, 2013.

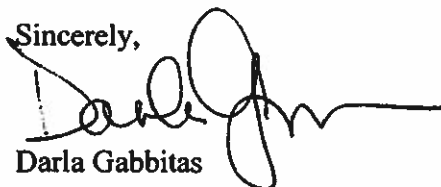
Kim Minneman
August 19, 2013
Page 2

Please indicate with sufficient specificity what documents have been redacted and the location of any redactions made in the documents provided so that we may continue our dialogue to obtain the requested information.

Third, in the materials responsive to Category 5, you provided two progress reports for 2004 and 2005. My request encompasses and I would expect to receive each annual progress report, including the most current one provided to NIEHS. Moreover, the progress reports provided indicate that the researchers provided raw data gathered during the study(s). This information falls under Category 1 ("All data supplied by or to the authors or researchers of the Study"); however, I would like to reiterate my request for the raw data reflected in any annual progress report.

Thank you in advance of your prompt response.

Sincerely,

A handwritten signature in black ink, appearing to read 'Darla Gabbitas', with a long horizontal flourish extending to the right.

Darla Gabbitas

Exhibit F



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Phone: 919-541-3411
Fax: 301-451-5756
E-mail: minneman@niehs.nih.gov

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233, MD K3-16
Research Triangle Park, NC 27709-2233

September 6, 2013

Darla J. Gabbitas
Bickel & Brewer
1717 Main Street, Suite 4800
Dallas, TX 75201

Re: FOI Case No. 41328

Dear Ms. Gabbitas:

This is our final response to your May 7, 2013, Freedom of Information Act (FOIA) request (amended from May 6, 2013) addressed to me. Your request was received in our office on May 14, 2013. You requested a copy of all non-exempt records maintained by the National Institute of Environmental Health Sciences ("NIEHS") regarding Study ES012199, supported in whole or in part by the NIEHS, which has resulted in published articles and which may have generated unpublished data and findings (the "Study"), as follows:

- (1) Grandjean, P., *Serum Vaccine Antibody Concentrations in Children Exposed to Perfluorinated Compounds*, 307 JAMA 4, 391-97 (2012). You provided a copy of the publication.
- (2) Grandjean, P., *Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations in children*, 12 Environmental Health 35 (2013). You provided a copy of the publication.

This request includes but should not be limited to the following information regarding the Study:

1. All data supplied by or to the authors or researchers of the Study;
2. All communications to or from the authors, researchers or anyone on either's behalf;
3. All records of funding, grants, stipends and payments by the NIEHS to the authors or researchers of the Study;
4. Any proposals, grant applications or other methods utilized to select this Study for support;
5. All drafts, interim reports, study updates or other indicia of study progress; and
6. All drafts, review copies or input requests regarding the final study report

On July 22, 2013, we made a partial release to you of 191 pages. This consisted of 23 pages responsive to Item 2 of your request, 155 pages responsive to Item 3, and 13 pages responsive to Item 5.

Regarding your August 19, 2013, letter concerning the partial release and redaction of information regarding the study's funding, including: (1) the source of private funding and (2) pending support for the study: there were no instances of those items in the responsive records. However, pending support is redacted on page 7 of the enclosed Just In Time Report, 2R01ES012199-06. Per your June 6, 2013, email, you withdrew your objections with the exception of receiving the project title of any pending support. There was no project title

Page 2 - Darla J. Gabbitas

included in the redacted section of the Just In Time Report. In addition, you wrote that my May 21, 2013, letter indicating possible redactions did not include references to unpublished articles and evaluative comments. However, they were redacted from the responsive records. I apologize that those were inadvertently omitted from my letter.

References to Unpublished Articles Redacted in the July 22, 2013 Partial Response

Responsive to Item 2: Correspondence for 5R01ES012199-04, page 4
Correspondence for 5R01ES012199-05, page 4

Evaluative Comments Redacted in the July 22, 2013 Partial Response

Responsive to Item 3: Grants Management Worksheets for 5R01ES02199-03, pages 3 and 6
Grants Management Worksheets for 5R01ES02199-04, pages 3 and 6
Grants Management Worksheets for 5R01ES02199-05, pages 7, 10, and 13
Grants Management Worksheets for 5R01ES02199-07, pages 5 and 9
Grants Management Worksheets for 5R01ES02199-08, page 8

In your August 19, 2013, letter, you stated that the progress reports provided "indicate that the researchers provided raw data gathered during the study(s)." I reviewed the progress reports again and did not locate a reference to raw data that was provided to NIEHS. I've confirmed that no raw data was provided to NIEHS.

Enclosed are 325 pages responsive to your request. This consists of:

Responsive to Item 2: Email for 5R01ES012199-05, 3 pages

Responsive to Item 4: Grant Application, 1R01ES012199-01A1, 69 pages
Summary Statement, 1R01ES012199-01A1, 7 pages
Application for Federal Assistance, 2R01ES012199-06, 180 pages
Just In Time Report, 2R01ES012199-06, 18 pages
Summary Statement, 1R01ES012199-06, 7 pages

Responsive to Item 5: Grant Progress Report, 5R01ES012199-04, 6 pages
Grant Progress Report, 5R01ES012199-05, 8 pages
ESNAP Report, 5R01ES012199-07, 13 pages
ESNAP Report, 5R01ES012199-08, 14 pages

It is Department of Health and Human Services (DHHS) policy to expunge evaluative comments, private phone numbers, percentage of effort (calendar months), references to unpublished articles, eRA Commons usernames (credentials), institutional base salaries, pending support, social security numbers, and birth dates wherever they appear throughout the grant material. Summary statements are expunged of the priority score, percentile, evaluation, opinion, and information pertaining to the budget recommendation. This information has been removed from the enclosed material. If you still feel that materials have been omitted that should have been made available to you, please write to me and I will consult with the NIH Freedom of Information Officer.

References to Unpublished Articles Redacted in the Enclosed Records

Responsive to Item 4: Grant Application, 1R01ES012199-01A1, pages 13, 23, 63, and 64
Application for Federal Assistance, 2R01ES012199-06, pages 21, 25, 28, 31, 35, 38, 42, 46, 158, 164, 167, and 169

Page 3 - Darla J. Gabbitas

Evaluative Comments Redacted in the Enclosed Records

Responsive to Item 2: Email for 5R01ES012199-05, pages 1-3

Responsive to Item 4: Grant Application, 1R01ES012199-01A1, pages 29 and 30
Summary Statement, 1R01ES012199-01A1, pages 2-5
Summary Statement, 1R01ES012199-06, pages 2-8

Requesters who ask for grant applications usually want to receive only material that will help in understanding the process that led to the awards or to improve their own methods of drafting grant applications. Requesters usually do not want material that applicants believe would harm them if released. We have found that the spirit of the FOIA can be enhanced through a spirit of cooperation among requesters of materials and those who submitted the materials.

In this instance, we asked the grantee for advice concerning patent rights and other confidential commercial or financial information and the material that we are furnishing reflects that advice. If you feel that materials have been omitted that should have been made available to you, please write to me and I will consult with the NIH Freedom of Information Officer.

The Division of Extramural Research and Training searched its files and no records responsive to your request under Items 1 and 6 were located. Under Item 1, this is due to the fact that it is not our practice to request data from grantees and we have not received any data from this grantee. We do not have any responsive records for Item 6 because this study is ongoing and a final study report will not be submitted until the grant has ended. While we believe that an adequate search of appropriate files was conducted for the records you requested, you have the right to appeal this determination that no records exist which would be responsive to part of your request. Should you wish to do so, your appeal must be sent within thirty (30) days of receipt of this letter to the Director, News Division, Office of the Assistant Secretary for Public Affairs, United States Department of Health and Human Services, following the procedures outlined in Subpart C of the HHS FOIA Regulations (<http://www.nih.gov/icd/od/foia/cfr45.htm>). Should you choose to send your appeal through the U.S. Postal Service, please mail it to Suite 920, 7700 Wisconsin Avenue, Bethesda, MD 20857. Should you choose to send your appeal through a private courier service, please send it to Suite 920, 7700 Wisconsin Avenue, Bethesda, MD 20814. Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

In certain circumstances provisions of the FOIA and DHHS FOIA Regulations allow us to recover part of the cost of responding to your request. Enclosed is an invoice for \$327.60 to cover the duplication costs associated with responding to your request. Because no unusual circumstances apply to the processing of your request, there are no charges for search time. Please note that National Institutes of Health now accepts electronic payments. Instructions are included with the invoice.

Sincerely,

Kim Minneman

Kim L. Minneman
Freedom of Information Coordinator

Enclosures:
Invoice (2 pages)
325 pages

Exhibit G

BICKEL & BREWER

ATTORNEYS AND COUNSELORS

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William A. Brewer, III
www.bickelbrewer.com

767 FIFTH AVENUE
50TH FLOOR
NEW YORK, NEW YORK 10153
(212) 469-1400

October 2, 2013

VIA FEDERAL EXPRESS MAIL

Director, News Division
Office of the Assistant Secretary for Public Affairs
United States Department of Health and Human Services
7700 Wisconsin Avenue, Suite 920
Bethesda, MD 20857

VIA ELECTRONIC MAIL: minneman@niehs.nih.gov

Kim Minneman
Freedom of Information Act Coordinator
National Institute of Environmental Health Sciences
111 T. W. Alexander Drive
Research Triangle Park, NC 27709

Re: **FREEDOM OF INFORMATION ACT APPEAL**
Freedom of Information Case No. 41328

Dear Director and Ms. Minneman:

Pursuant to 45 C.F.R. § 5.34, this letter is an appeal from the National Institute of Environmental Health Science's ("NIEHS") September 6, 2013 final response ("Final Response") to the above-referenced FOIA request. For the following reasons, we request that NIEHS produce progress reports from 2008-10, conduct an independent assessment of the information redacted from the 325 pages of documents produced in the Final Response, and produce complete and unredacted copies of all responsive documents.

First, in the materials responsive to Category 5 of this request, NIEHS has only provided progress reports for 2004-07 and 2011-12. Progress reports for 2008-10 have yet to be produced. Our request encompasses, and we would expect to receive, these unproduced reports. As such, we request that NIEHS produce progress reports from 2008-10.

Second, in the Final Response, NIEHS stated that it asked the grantee for advice concerning patent rights and other confidential commercial or financial information and that the material we have received reflects that advice. Consultation with the submitter, however, is merely "appropriate as one step in the evaluative process," it is "not sufficient to satisfy [an

News Division Director and Kim Minneman
October 2, 2013
Page 2

agency's] FOIA obligations.”¹ Consequently, an agency is “required to determine for itself whether the information in question should be disclosed.”² It is unclear to what extent such advice was considered; however, we are mindful that when a submitter makes his own redactions in response to a FOIA request, that does not relieve an agency of the obligation to make an independent assessment as to the applicability of Exemption 4. Accordingly, we appeal to ensure an independent assessment of the redacted information, with consideration given to the below.

Third, significant portions of the 325 pages of documents produced in the Final Response have been redacted as “confidential commercial information” under FOIA Exemption 4, which exempts from production all “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.”³ The redactions include but are not limited to:

Grant Application, 1R01ES012199-01A1 - Pages 31, 38-43
Application for Federal Assistance, 2R01ES012199-06 - Pages 24, 34, 37, 45, 67, 86, 121-22, 144-48, 150-56, 171
Just In Time Report, 2R01ES012199-06 - Page 14
Grant Progress Report, 5R01ES012199-04 - Page 3
Grant Progress Report, 5R01ES012199-05 - Pages 3, 4
ESNAP Report, 5R01ES012199-07 - Page 12
ESNAP Report, 5R01ES012199-08 - Pages 11, 12

We believe that we are entitled to copies of all withheld documents and a full and complete version of the redacted documents. For information to fall under Exemption 4, it must be (a) commercial or financial, (b) obtained from a person, and (c) privileged or confidential.

In determining what constitutes “commercial or financial” information, the Court of Appeals for the District of Columbia has firmly held that the terms should be given their “ordinary meaning,” and that records are commercial so long as the submitter has a “commercial interest” in them.⁴ The D.C. Circuit has recognized the possibility that a grantee could “conceivably be shown to have a commercial or trade interest in his research,” but emphasized

¹ *Lee v. FDIC*, 923 F. Supp. 451, 455 (S.D.N.Y. 1996).

² *Lee*, 923 F. Supp. at 451.

³ 5 U.S.C. § 552(b)(4) (2006).

⁴ *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983).

News Division Director and Kim Minneman
October 2, 2013
Page 3

that “the burden of showing” such an interest “was on the agency.”⁵ We have received no evidence to suggest that Dr. Philippe Grandjean (“Grandjean”) is associated with any profit-oriented ventures necessary to qualify him as a commercial research scientist.⁶ In fact, his institutional affiliation with Harvard makes this possibility very unlikely.⁷ The same should be said of the noncommercial nature of the information itself. The D.C. Circuit has held that designs for research and the resulting data, when submitted by a scientist in a non-commercial setting, are not commercial or financial information within the meaning of FOIA Exemption 4.⁸

The final requirement is that the information is “privileged or confidential.” Information is confidential in this case if its disclosure would “cause substantial harm to the competitive position of the person from whom the information was obtained.”⁹ In such a case, parties opposing disclosure “need not show actual competitive harm; evidence showing actual competition and the likelihood of substantial competitive injury” is sufficient.¹⁰ However, “conclusory and generalized allegations of substantial competitive harm are . . . unacceptable and cannot support an agency’s decision to withhold requested [information].”¹¹ Here, there is nothing to suggest that actual competition exists in the field of study for environmental chemicals. According to Grandjean, “immunotoxicity is rarely considered in risk assessment of

⁵ *Washington Research Project, Inc. v Department of Health, Education & Welfare*, 504 F.2d 238, 245 (D.C. Cir. 1974).

⁶ *Compare Physicians Committee For Responsible Medicine v. NIH*, 326 F. Supp. 2d 19, 24 (D.D.C. 2004) (concluding that a noncommercial scientist’s research did “not amount to commercial information” after finding that the scientist “never manufactured or marketed any drug . . . that was produced as a result of his research” and that “none of [his] research results have been marketed or used”) with *Cooper v. U.S. Dep’t of the Navy*, No. 05-2252, 2007 WL 1020343, at *3-4 (D.D.C. Mar. 30, 2007) (determining that a professor had commercial interest in his research, as demonstrated by his filing of patent applications and formation of for-profit company).

⁷ See *Physicians Committee*, 326 F. Supp. 2d at 24 (“The fact that [the research scientist] was engaged in research for the university renders the possibility of a trade interest in his research design remote.”).

⁸ *Washington Research Project, Inc. v Department of Health, Education & Welfare*, 504 F.2d 238, 245 (D.C. Cir. 1974) (finding that design for research devised by a scientist in a noncommercial setting and submitted in grant applications was not a commercial information, regardless of whether it was contained in initial grant applications or supplement or renewal applications or progress reports); see also *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 704 F.2d 1280 (D.C. Cir. 1983) (finding that results of medical care evaluation studies were not commercial information exempted under FOIA).

⁹ *Physicians Committee For Responsible Medicine v. NIH*, 326 F. Supp. 2d 19, 26 (D.D.C. 2004) (quoting *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 704 F.2d 1280, 1290 (D.C. Cir. 1983)).

¹⁰ *Pub. Citizen Health Research Grp.*, 704 F.2d at 1291.

¹¹ *Id.*

News Division Director and Kim Minneman
October 2, 2013
Page 4

environmental chemicals.”¹² He continues that “[a] main problem is the absence of systematic epidemiological evidence.”¹³ Grandjean’s own words indicate a lack of study in the field, which in turn suggests a lack of competition. Furthermore, there is no indication of a likelihood of substantial competitive injury. Courts have found that assertions of work being performed on similar projects or concerns that disclosure may affect the grantee’s ability to publish results that have already been disclosed are insufficient justification for withholding information.¹⁴

Therefore, we assert that the information withheld or redacted from the Final Response is neither commercial nor confidential. Accordingly, we request that NIEHS produce all withheld documents and a complete and unredacted copies of all responsive materials.

In light of the foregoing, this Appeal seeks production from NIEHS of the withheld progress reports from 2008-10, an independent assessment of the information redacted from the 325 pages of documents produced in the Final Response, and production of complete and unredacted copies of these documents.

Sincerely,

A handwritten signature in black ink that reads "William A. Brewer III" followed by a stylized monogram "WAB".

William A. Brewer, III

¹² Application for Federal Assistance, 2R01ES012199-06, p. 8.

¹³ *Id.*


¹⁴ *Physicians Committee*, 326 F. Supp. 2d at 26-27.

AFFIDAVIT OF DELIVERY

This is to certify that the enclosed document (FOIA Appeal) was delivered on Friday 10/4/13 at 12:30-12:45PM by our contracted notary Karen Wynn.

The document was delivered to and received by Kristen Rancout of PSC at the following address: 7700 Wisconsin Ave. Suite 920 Bethesda, MD 20857

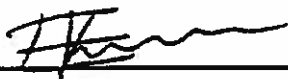
ATTESTED TO BY


Phillip Mossler

State of CA

County of SAN MATEO

Sworn or subscribed before me by PHILLIP MOSSLER



Notary Public

(seal)

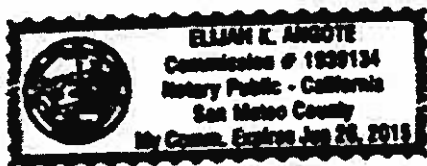


Exhibit H

BICKEL & BREWER

ATTORNEYS AND COUNSELORS

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William A. Brewer, III
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January 3, 2013

Director, News Division
Office of the Assistant Secretary for Public Affairs
United States Department of Health and Human Services
7700 Wisconsin Avenue, Suite 920
Bethesda, MD 20857

VIA ELECTRONIC MAIL: minneman@niehs.nih.gov

Kim Minneman
Freedom of Information Act Coordinator
National Institute of Environmental Health Sciences
111 T. W. Alexander Drive
Research Triangle Park, NC 27709

Re: **FREEDOM OF INFORMATION ACT APPEAL**
Freedom of Information Case No. 41328

Dear Director and Ms. Minneman:

We write regarding the status of our appeal concerning the above-referenced FOIA request.¹ It has been three months since we appealed the National Institute of Environmental Health Science's ("NIEHS") final response to the above-referenced request.² To date, we have received no response from NIEHS regarding our appeal. Under federal law, we were entitled to a response within 20 days of your receipt of our appeal.³

¹ See Letter from W. Brewer, III to News Division Director and K. Minneman (Oct. 2, 2013) ("FOIA Appeal") (attached).

² See Email from Barbara Morgan to Kim Minneman (Oct. 3, 2013, 19:30 EST) (attaching FOIA Appeal).

³ See 5 U.S.C. § 552(a)(6)(A)(ii).

News Division Director and Kim Minneman
January 3, 2013
Page 2

If you do not respond to our appeal by January 31, 2014, we will be forced to bring an action under the Administrative Procedure Act to obtain necessary relief, which may include attorney's fees and costs.⁴

If you have any questions regarding this letter or any issue raised in our appeal, please do not hesitate to contact me.

Sincerely,


William A. Brewer, III 

⁴ See § 552(a)(4)(E).

BICKEL & BREWER

ATTORNEYS AND COUNSELORS

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October 2, 2013

VIA FEDERAL EXPRESS MAIL

Director, News Division
Office of the Assistant Secretary for Public Affairs
United States Department of Health and Human Services
7700 Wisconsin Avenue, Suite 920
Bethesda, MD 20857

VIA ELECTRONIC MAIL: minneman@niehs.nih.gov

Kim Minneman
Freedom of Information Act Coordinator
National Institute of Environmental Health Sciences
111 T. W. Alexander Drive
Research Triangle Park, NC 27709

Re: **FREEDOM OF INFORMATION ACT APPEAL**
Freedom of Information Case No. 41328

Dear Director and Ms. Minneman:

Pursuant to 45 C.F.R. § 5.34, this letter is an appeal from the National Institute of Environmental Health Science's ("NIEHS") September 6, 2013 final response ("Final Response") to the above-referenced FOIA request. For the following reasons, we request that NIEHS produce progress reports from 2008-10, conduct an independent assessment of the information redacted from the 325 pages of documents produced in the Final Response, and produce complete and unredacted copies of all responsive documents.

First, in the materials responsive to Category 5 of this request, NIEHS has only provided progress reports for 2004-07 and 2011-12. Progress reports for 2008-10 have yet to be produced. Our request encompasses, and we would expect to receive, these unproduced reports. As such, we request that NIEHS produce progress reports from 2008-10.

Second, in the Final Response, NIEHS stated that it asked the grantee for advice concerning patent rights and other confidential commercial or financial information and that the material we have received reflects that advice. Consultation with the submitter, however, is merely "appropriate as one step in the evaluative process," it is "not sufficient to satisfy [an

News Division Director and Kim Minneman
 October 2, 2013
 Page 2

agency's] FOIA obligations.”¹ Consequently, an agency is “required to determine for itself whether the information in question should be disclosed.”² It is unclear to what extent such advice was considered; however, we are mindful that when a submitter makes his own redactions in response to a FOIA request, that does not relieve an agency of the obligation to make an independent assessment as to the applicability of Exemption 4. Accordingly, we appeal to ensure an independent assessment of the redacted information, with consideration given to the below.

Third, significant portions of the 325 pages of documents produced in the Final Response have been redacted as “confidential commercial information” under FOIA Exemption 4, which exempts from production all “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.”³ The redactions include but are not limited to:

Grant Application, 1R01ES012199-01A1 - Pages 31, 38-43
 Application for Federal Assistance, 2R01ES012199-06 - Pages 24, 34, 37, 45, 67, 86, 121-22, 144-48, 150-56, 171
 Just In Time Report, 2R01ES012199-06 - Page 14
 Grant Progress Report, 5R01ES012199-04 - Page 3
 Grant Progress Report, 5R01ES012199-05 - Pages 3, 4
 ESNAP Report, 5R01ES012199-07 - Page 12
 ESNAP Report, 5R01ES012199-08 - Pages 11, 12

We believe that we are entitled to copies of all withheld documents and a full and complete version of the redacted documents. For information to fall under Exemption 4, it must be (a) commercial or financial, (b) obtained from a person, and (c) privileged or confidential.

In determining what constitutes “commercial or financial” information, the Court of Appeals for the District of Columbia has firmly held that the terms should be given their “ordinary meaning,” and that records are commercial so long as the submitter has a “commercial interest” in them.⁴ The D.C. Circuit has recognized the possibility that a grantee could “conceivably be shown to have a commercial or trade interest in his research,” but emphasized

¹ *Lee v. FDIC*, 923 F. Supp. 451, 455 (S.D.N.Y. 1996).

² *Lee*, 923 F. Supp. at 451.

³ 5 U.S.C. § 552(b)(4) (2006).

⁴ *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983).

News Division Director and Kim Minneman

October 2, 2013

Page 3

that “the burden of showing” such an interest “was on the agency.”⁵ We have received no evidence to suggest that Dr. Philippe Grandjean (“Grandjean”) is associated with any profit-oriented ventures necessary to qualify him as a commercial research scientist.⁶ In fact, his institutional affiliation with Harvard makes this possibility very unlikely.⁷ The same should be said of the noncommercial nature of the information itself. The D.C. Circuit has held that designs for research and the resulting data, when submitted by a scientist in a non-commercial setting, are not commercial or financial information within the meaning of FOIA Exemption 4.⁸

The final requirement is that the information is “privileged or confidential.” Information is confidential in this case if its disclosure would “cause substantial harm to the competitive position of the person from whom the information was obtained.”⁹ In such a case, parties opposing disclosure “need not show actual competitive harm; evidence showing actual competition and the likelihood of substantial competitive injury” is sufficient.¹⁰ However, “conclusory and generalized allegations of substantial competitive harm are . . . unacceptable and cannot support an agency’s decision to withhold requested [information].”¹¹ Here, there is nothing to suggest that actual competition exists in the field of study for environmental chemicals. According to Grandjean, “immunotoxicity is rarely considered in risk assessment of

⁵ *Washington Research Project, Inc. v. Department of Health, Education & Welfare*, 504 F.2d 238, 245 (D.C. Cir. 1974).

⁶ *Compare Physicians Committee For Responsible Medicine v. NIH*, 326 F. Supp. 2d 19, 24 (D.D.C. 2004) (concluding that a noncommercial scientist’s research did “not amount to commercial information” after finding that the scientist “never manufactured or marketed any drug . . . that was produced as a result of his research” and that “none of [his] research results have been marketed or used”) with *Cooper v. U.S. Dep’t of the Navy*, No. 05-2252, 2007 WL 1020343, at *3-4 (D.D.C. Mar. 30, 2007) (determining that a professor had commercial interest in his research, as demonstrated by his filing of patent applications and formation of for-profit company).

⁷ See *Physicians Committee*, 326 F. Supp. 2d at 24 (“The fact that [the research scientist] was engaged in research for the university renders the possibility of a trade interest in his research design remote.”).

⁸ *Washington Research Project, Inc. v. Department of Health, Education & Welfare*, 504 F.2d 238, 245 (D.C. Cir. 1974) (finding that design for research devised by a scientist in a noncommercial setting and submitted in grant applications was not a commercial information, regardless of whether it was contained in initial grant applications or supplement or renewal applications or progress reports); see also *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 704 F.2d 1280 (D.C. Cir. 1983) (finding that results of medical care evaluation studies were not commercial information exempted under FOIA).

⁹ *Physicians Committee For Responsible Medicine v. NIH*, 326 F. Supp. 2d 19, 26 (D.D.C. 2004) (quoting *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 704 F.2d 1280, 1290 (D.C. Cir. 1983)).

¹⁰ *Pub. Citizen Health Research Grp.*, 704 F.2d at 1291.

¹¹ *Id.*

BICKEL & BREWER

News Division Director and Kim Minneman
October 2, 2013
Page 4

environmental chemicals.”¹² He continues that “[a] main problem is the absence of systematic epidemiological evidence.”¹³ Grandjean’s own words indicate a lack of study in the field, which in turn suggests a lack of competition. Furthermore, there is no indication of a likelihood of substantial competitive injury. Courts have found that assertions of work being performed on similar projects or concerns that disclosure may affect the grantee’s ability to publish results that have already been disclosed are insufficient justification for withholding information.¹⁴

Therefore, we assert that the information withheld or redacted from the Final Response is neither commercial nor confidential. Accordingly, we request that NIEHS produce all withheld documents and a complete and unredacted copies of all responsive materials.

In light of the foregoing, this Appeal seeks production from NIEHS of the withheld progress reports from 2008-10, an independent assessment of the information redacted from the 325 pages of documents produced in the Final Response, and production of complete and unredacted copies of these documents.

Sincerely,

William A. Brewer III / WM

William A. Brewer, III

¹² Application for Federal Assistance, 2R01ES012199-06, p. 8.

¹³ *Id.*

¹⁴ *Physicians Committes*, 326 F. Supp. 2d at 26-27.

Barbara Morgan

From: Barbara Morgan
Sent: Thursday, October 03, 2013 6:30 PM
To: minneman@niehs.nih.gov
Subject: Appeal to NIEH response dated September 6, 2013 to FOIA request Case No. 41328
Attachments: Appeal to NIEH response dated September 6, 2013 to FOIA request Case No. 41328.PDF

Dear Ms. Minneman:

Please see the attached correspondence in connection with Freedom of Information Case. No. 41328.

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.